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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	27

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/832,443	Wolpe And Tsyrlova
Examiner	**Art Unit**
Mary B. Tung	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on 11/7/00, 12/13/00, 4/16/01

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) 47-52 and 91-99 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) 47-49, 51, 52, and 91-99 is/are rejected.

7) [X] Claim(s) 50 is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirem

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [ ] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22

18) [ ] Interview Summary (PTO-413) Paper No(s) _____

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other

DETAILED ACTION

1. Claims 1-90 were originally presented, claims 1-46 and 53-90 were drawn to a non-elected invention.

2. Non-elected claims 1-46 and 53-90 were cancelled in the paper filed 11/7/2000, Paper No. 21.

3. Claims 91-99 were added in Paper No. 21.

4. Claims 47-52 and 91-99 are pending.

Priority

5. This application repeats a substantial portion of prior Application No. 08/535,882, filed 9/28/95 and issued as US Patent No. 5,939,391, issued 8/17/99, and prior Application No. 08/316,424, filed 9/30/94 and issued as US Patent No. 6,022,848, issued 2/8/00 and adds claims and additional disclosure not presented in the prior applications. Since this application names an inventor or inventors named in the prior applications, it may constitute a continuation-in-part of the prior applications. Should Applicant desire to obtain the benefit of the filing date of the prior applications, attention is directed to 35 U.S.C. 120 and 37 C.F.R. 1.78.

Election/Restriction

6. Applicant has elected in Paper No. 26, the species "2a", (SEQ ID NOS: 1 and 2).

In light of the amendment filed 4/19/2001, Paper No. 26, only the following rejections remain:

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

8. Claims 47-49 and 51 and new claims 95 and 96 stand rejected under 35 U.S.C. 102(e) as being anticipated by Petrov, et al. (US Patent #5,786,334).

9. The '334 patent teaches a method of stimulating the proliferation of peripheral blood lymphocytes and antibody production from lymph node cells (see col. 1, lines 47-51 and col. 2, lines 42-45) by contact with alpha and beta chains of hemoglobin, as recited in claim ***47***, which are also taught by the '334 patent to have opioid activity (see col. 1, lines 55-60 and cols. 5 and 6). **Note:** the word "having" is interpreted as open, thus any sequence of any size would read upon the claimed invention, if the recited sequences are part of the reference sequence. Also, the opioid activity of the taught sequences are assumed to have the ability to bind to opiate receptors, as recited in claim ***51***. The fragments taught by the '334 patent are assumed to be included in the recited designation of "INPROL" as recited in claim ***47***. The term "stem cells" are interpreted as being cells capable of long-term culture as defined in the specification on page 63, lines 17 and 18. Therefore, the reference teachings anticipate the claimed invention. The limitation of the last line of claim ***47***, wherein the stem cells in the step can generate multiple lineages and other stem cells and whereby the differentiation of the stem cells is stimulated lend no patentable weight to the claims are new uses for an old method and lend no patentable weight to the claims. It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See In re Woodruff 16 USP2d 1934, 1936, (Fed. Cir. 1990).

10. The Applicants' arguments concerning progenitor cell definition are not persuasive since the claims do not recite progenitor cells. The Applicant's arguments concerning the definition of hematopoietic stem cells is unpersuasive because the cell populations of the instant application would be encompassed by the definition.

The following are new grounds for rejection:

11. Claims 47-49, 51 and 52 and new claims 91-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsyrlova, et al. (US Patent #5,939,391).

12. Claims 1 and 2 claim SEQ ID NOS: 1 and 2, wherein SEQ ID NO: 2 cys residues form a disulfide bond and col. 4, lines 41-43 teaches INPROL as a stem cell proliferation inhibitor, wherein INPROL includes alpha, beta, gamma, delta, epsilon, zeta or mixtures of hemoglobin (see col. 10) and a method of inhibiting hematopoietic stem cell proliferation (see col. 5). The recitation of the instant application whereby the differentiation of the stem cells is stimulated lends no patentable weight to the claims is a new use for an old method and lends no patentable weight to the claims. It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See In re Woodruff 16 USP2d 1934, 1936, (Fed. Cir. 1990).

13. Claims 47, 48, 51, 52 , 95 and 96 are rejected under 35 U.S.C. 102(e) as being anticipated by Kozlov, et al. (US Patent #6,022,848).

see claim 5 of Kozlov

14. The 848 patent teaches and claims a method of inhibiting stem cell proliferation by contacting hematopoietic cells using a composition comprising the alpha, beta, gamma, delta, epsilon, zeta or mixtures of hemoglobin (see claims 1-3), INPROL as a stem cell proliferation inhibitor, wherein INPROL includes alpha and beta chains of hemoglobin (see col. 8) and a method of inhibiting hematopoietic stem cell proliferation (see col. 8). The recitation of the instant application whereby the differentiation of the stem cells is stimulated lends no patentable weight to the claims is a new use for an old method and lends no patentable weight to the claims. It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See In re Woodruff 16 USP2d 1934, 1936, (Fed. Cir. 1990)

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

16. Claims 47-49, 51, 52 and 91-99 are rejected under the judicially created doctrine of double patenting over claims 1-3 and 12 of U. S. Patent No. 6,022,848 in view of US Patent No. 5,939,391,

17. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 848 patent teaches and claims a method of inhibiting stem cell proliferation by contacting hematopoietic cells using a composition comprising the alpha, beta, gamma, delta, epsilon, zeta or mixtures of hemoglobin (see claims 1-3), INPROL as a stem cell proliferation inhibitor, wherein INPROL includes alpha and beta chains of hemoglobin (see col. 8) and a method of inhibiting hematopoietic stem cell proliferation (see col. 8). The '391 patent teaches SEQ ID NOS: 1 and 2 (claims 1 and 2), wherein SEQ ID NO: 2 cys residues form a disulfide bond and col. 4, lines 41-

43 teaches INPROL as a stem cell proliferation inhibitor, wherein INPROL includes alpha, beta, gamma, delta, epsilon, zeta or mixtures of hemoglobin (see col. 10) and a method of inhibiting hematopoietic stem cell proliferation (see col. 5). One of ordinary skill in the art would have been motivated to use the INPROL composition of the '391 patent in the method of the '848 patent in light of the teaching of the '391 patent of the same method of inhibiting stem cell proliferation. One of ordinary skill in the art would easily recognize the equivalence of the two INPROL compositions and would substitute the INPROL composition of the '381 patent for the INPROL composition claimed by the '848 patent. The recitation of the instant application whereby the differentiation of the stem cells is stimulated lends no patentable weight to the claims is a new use for an old method and lends no patentable weight to the claims. It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See In re Woodruff 16 USP2d 1934, 1936, (Fed. Cir. 1990).

Conclusion

18. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

June ~~30~~ 29, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

MARY BETH TUNG, PH.D
PATENT EXAMINER